REMARKS

The application has been amended to more clearly identify the inventive subject matter. More specifically, the application has been amended to correct clerical errors in the specification pointed out by the Examiner.

Restriction Requirement

The Examiner has restricted the application to two inventions under 35 U.S.C. §121. Group I represent claims 1-3, 5-10, and 17-20, drawn to an endoprosthesis, classified in class 623. subclass 1.13. Group II includes claims 4 and 11-16, drawn to a method of making a porous polymer, classified in class 524, subclass 903.

The Examiner further states:

> Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case the endoprosthesis may be made by another process such as laser removal, punching or cutting pores, salt leaching, or polymer's other than siloxane extracted. The method of making a polymer may form polymers that may be used as products other than endoprostheses, such as circuit boards, surgical apparel or cables.

Applicants have provisionally elected to prosecute the invention of Group I, claims 1-3, 5-10, and 17-20. Applicants confirm this election and reserve the right to prosecute Group II in a later application.

Objection to the Abstract

The Examiner has objected to the abstract for being too short in length. Applicants herewith submit a new abstract in compliance with the requirements. Withdrawal of the

objection is respectfully requested.

Objection to the Drawings

The Examiner has objected to the drawings as failing to comply with 37 C.F.R. §1.84(p)(5) because they do not include reference numbers 11 and 13 mentioned in the description. Applicants submit substitute drawings herewith including reference Nos. 11 and 13. Withdrawal of the objection is respectfully requested.

Applicants have further amended the specification, specifically paragraphs [0050], [0052], and [0062] to correctly indicate that reference number 12 is used only to refer to the stent.

The Examiner has further objected to Figure 8 because it has not been designated at prior art. Applicant herein attaches a revised Figure 8 with such designation. Withdrawal of the objection is respectfully requested.

Double Patenting Rejection

Claims 5-10 and 17-20 have been provisionally rejected by the Examiner under 35 U.S.C. §101 as claiming the same invention as that of claims 1-6 and 13-16 of co-pending application No. 09/704,494. Applicants herein cancel claims 5-10 and 17-20.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 1 and 3 under 35 U.S.C. §102(e) as being anticipated by Zilla et al. (WO 00/30564) (hereinafter "Zilla"). More specifically, the Examiner states, "Zilla discloses a medical device or vascular graft (page 4, lines 12-13) comprising a tubular extrudate (page 11, lines 1-5) comprising a PTFE matrix (page 5, lines 15-17) having domains of an extractable polymeric material (page 4, lines 3-4), wherein subjecting the extrudate is exposed to a dissolving medium or degrading temperature to extract a portion of the polymer, forming pores (page 6, lines 21-23)."

The rejection is respectfully traversed. Zilla discloses a vascular prosthesis including a structure having an inner-connected helically oriented channel with a porosity to allow oriented in-growth of connective tissue into a wall of the prosthesis. The graft material comprising the vascular prosthesis in Zilla is polyurethane. Polytetrafluoroethylene is not used as the graft material, but rather may be used in a limited capacity as a "non-extractable fiber." See Zilla, page 5, lines 9-20.

It is not disclosed, taught, or suggested in Zilla to provide a vascular graft having a PTFE matrix with domains of an extractable polymeric material as claimed in the present invention. Any suggestion of such a disclosure or teaching or suggestion in Zilla is contrary to the alleged invention of Zilla.

The Examiner has selected various passages of Zilla which disclose the materials present in the present invention. The disclosure of Zilla however, provides that PTFE is used in a substantially different role in Zilla. Specifically, PTFE may be used as a "non-extractable fiber". A non-extractable fiber is any polymeric or other fiber material that is not extractable by the fiber extraction solvent of Zilla. This is in stark contrast to the graft material of Zilla which is any polymeric or other material that can be dissolved in a suitable solvent and resolidified after graft manufacture by air drying, phase inversion or combinations thereof. Examples of suitable graft materials include thermoplastic elasotmers including thermoplastic polyurethanes, e.g. Pellethane, Biomer-type polyurethanes, Chronoflex, and Hydrothane. See page 5, lines 27-31 of Zilla.

There is no suggestion to use a tubular extruded PTFE matrix as presently claimed as a vascular graft in Zilla. The rejection is respectfully traversed, withdrawal and reconsideration is respectfully requested.

The Examiner has also rejected claims 1 and 3 under 35 U.S.C. §102(e) as being anticipated by WO 87/02996 (Mitchell). More particularly, the Examiner states:

> Mitchell discloses a medical device or vascular graft (page 2, lines 19-20) comprising a tubular extrudate comprising a PTFE matrix having domains of an extractable polymeric material, wherein subjecting the extrudate is exposed to a dissolving medium or degrading temperature to extract a portion of the polymer, forming pores (Tables 4, 5; page 13, lines 1-11).

Mitchell provides an interpenetrating polymeric network including a polymer structure with node and fibrils and a polysiloxane. In all applications of Mitchell, however, the IPN with the polysiloxane remains intact. Component (a) of Mitchell is listed as being any polymer capable of being stretched, drawn, or expanded so as to obtain a microstructure characterized by nodes interconnected by very small fibrils. It is preferred to use PTFE. See Mitchell, page 7, lines 5-18. This embodiment is designed to be used in medical devices.

In another embodiment of Mitchell, however, it is contemplated that a first polymer network which is not stretched may be used with a second polymer network comprising of polydiorganosilaxane. See page 13, line 1-20 of Mitchell. This embodiment is not used in medical devices. It is instead used in such applications as filters, pump packing, insulation for electrical cables, and as laminates used for manufacture of breathable wearing apparel. See page 13, lines 10-15 of Mitchell. In both embodiments, the polysiloxane is not extracted.

Mitchell therefore does not disclose each and every element of the claimed invention, as it does not disclose a medical device or vascular graft as recited in claims 1 and 3 respectively.

Applicants further note that while Mitchell discloses "extraction experiments" detailed in Table 5 of Mitchell on page 21, these experiments were conducted merely, "to show that the silicone compositions did cure into the PTFE matrix." See Mitchell, page 20, lines 1-10. They were certainly never intended for use as a vascular graft or medical device. The reference therefore fails as a reference under 35 U.S.C. §102.

The rejection is respectfully traversed. Withdrawal and reconsideration are respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner has rejected claim 2 under 35 U.S.C. §103(a) as being unpatentable over Zilla in view of Dereume, et al. (U.S. Patent No. 5,639,278). More particularly, the Examiner states:

> Zilla discloses a medical device comprising a tubular extrudate, commonly known as a graft comprising a PTFE matrix having domains of an extractable polymeric material. Zilla does not teach however, a stent combined with a graft. Dereume teaches combining an axially positioned stent combined with a graft, in order to provide increased support by the stent, enhanced tissue ingrowth by the graft, and means to cover an aneurysm in an artery or vein.

The rejection is respectfully traversed. In addressing Zilla as a §102 reference, Applicants have already described in detail that Zilla does not provide a vascular graft having a PTFE matrix with domains of an extractable polymeric material as claimed in the present invention. For the sake of brevity, Applicants will not repeat the discussion on Zilla.

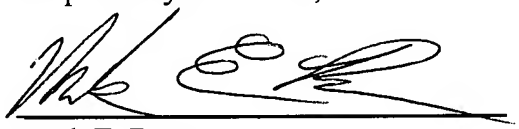
For the same reasons that Zilla fails as a reference under 35 U.S.C. §102, the combination of Zilla and Dereume fail as a proper combination under 35 U.S.C. §103. Dereume fails to cure the deficiencies of Zilla. The combination of Zilla and Dereume therefore fails to disclose each and every element of the claimed invention.

Still further, nothing in Zilla or Dereume teaches or suggests the invention as claimed. Withdrawal and reconsideration of the rejection is therefore respectfully requested.

The Examiner has also rejected claims 5-15 and 17-20 under 35 U.S.C. §103(a) as being unpatentable over Mitchell in view of Dereume. Applicants have cancelled claims 5-10 and 17-20, and claims 11-15 have been cancelled with traverse in response to the restriction requirement. The rejection is therefore moot.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,



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VERSION OF AMENDMENT WITH MARKING SHOWING CHANGES MADE

ABSTRACT:

~~Non-expanded porous PTFE materials and products are disclosed. More particularly, grafts and stent-grafts incorporating the non-porous PTFE materials are described.~~

A non-expanded porous polytetrafluoroethylene substrate is used in an endoprosthesis device. An elongate radially expandable tubular stent may also be included with the porous PTFE substrate, and together they form the endoprosthetic device. A method of making the porous polytetrafluoroethylene entails a novel method including a polymeric material in PTFE and thereafter removing the polymeric material to form the porous structure. The PTFE structure does not have nodes and fibrils.

IN THE SPECIFICATION:

Please replace paragraph [0050] on page 14 with the following paragraph:

[0050] Fig. 3 illustrates generally at 10 an intraluminal device in the form of a stent 12 as shown in fig. 1 having a cover 14 on the outer surface of the stent 12 and liner 16 on the inner surface, both of which may be of the porous structure shown below in fig. 7. The stent may optionally have only a cover 14 as shown in fig. 5, or only a liner 16 as shown in fig. 6, or both as shown in fig. 3. In a preferred embodiment, the stent has both a cover 14 and a liner 16. The liner, cover, or both, will be referred to hereinafter collectively as a cover or covering. The cover provides an effective barrier about the stent 12 preventing excessive cell or tissue ingrowth or thrombus formation through the expanded wall of the stent 12.

Please replace paragraph [0052] on page 14 with the following paragraph:

[0052] Fig. 1 is a more detailed illustration of stent ~~10~~ 12 and shows generally an elongate tube. The body of stent 12 defines an opposed interior surface 11 and an exterior surface 13 and is formed of a generally open configuration having a plurality of openings or passages provided for longitudinal flexibility of the stent as well as permitting the stent to be radially expanded once deployed in the body lumen. Both the interior surface 11 and the exterior surface 13 may have the porous PTFE covering of the present invention. On the interior surface the covering is referred to as the liner 12 as shown in Fig. 1 and on the exterior surface it is referred to as a cover 14 as shown in Fig. 1.

Please replace paragraph [0062] on pages 16-17 with the following paragraph:

[0062] As discussed above, the stent may be covered on the interior surface 11 of the stent ~~10~~ 12, the exterior surface 13 of the stent ~~10~~ 12. or both. Preferably, the stent ~~10~~ 12 is covered on both the interior 11 and the exterior 13 surfaces of the stent ~~10~~ 12. Having the entire surface of the stent ~~10~~ 12 covered with the porous PTFE of the present invention provides an effective barrier about the stent ~~10~~ 12 preventing excessive cell or tissue growth, or thrombus formation through the expanded wall of a tubular stent ~~10~~12.